

**DIVISION OF OTC DRUG PRODUCTS
CENTER FOR DRUG EVALUATION AND RESEARCH**

ANNOUNCEMENT OF OTC DRUG FEEDBACK MEETING

BETWEEN: Representatives of FDA

and

Bayer Corporation

**Joanne Robinett, Director, Regulatory Affairs
Harry Cocolas, Ph.D., Manager, Formulations Department
Mary Rose Salvacion, Manager, Regulatory Affairs
Andrew Snoddy, Ph.D., Associate Director, Clinical Research
Uma Tripathi, Ph.D., Vice President, Scientific Affairs**

**TOPIC: Inclusion of Phenylephrine Bitartrate as an active ingredient in the
"Cold, Cough, Allergy, Bronchodilator, Antiasthmatic Drug Products
For Over-the-Counter Human Use; Final Monograph for OTC Nasal
Decongestant Drug Products" (Docket No. 76N-052N)**

DATE: February 15, 2002

TIME: 9:30 a.m.

**LOCATION: Conference Room S-300
9201 Corporate Boulevard
Rockville, Maryland**

Pursuant to the agency's policy statement published in the **FEDERAL REGISTER** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050) and February 4, 1985 (50 FR 4916), which includes provisions for agency meetings with industry or other interested persons, this feedback meeting is being announced.

All feedback meetings are open to the public and no prior reservation is necessary. For further information or to reconfirm that the meeting has not been rescheduled or canceled, call Babette Merritt, 301-827-2241.

ATTENTION: JENNIE BUTLER

cc: Docket No. 80N-0295

DATE FORWARDED: _____

80N-0295

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M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

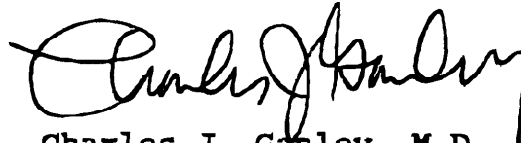
DATE: February 4, 2002

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 80N-0295

TO: Dockets Management Branch, HFA-305

- ☒ The attached material should be placed on public display under the above referenced Docket No.
- ☐ This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment

Post-it® Fax Note 7671		Date <u>2/4/02</u>	# of pages <u>2</u>
To <u>Jennie Butler</u>		From <u>Linda Roberts</u>	
Co./Dept. <u>DMB</u>		Co. <u>OTC</u>	
Phone # <u>7-6880</u>		Phone # <u>7-2375</u>	
Fax # <u>7-6870</u>		Fax # <u>7-2315</u>	